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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,883	11/30/2000	Paul E. Harris	62682/JPW/PT	1468

7590 07/30/2003

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/726,883

Applicant(s)

Harris et al.

Examiner

G.R. Ewoldt, Ph.D.

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 3, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment, filed 6/02/03, has been entered.

2. Claims 1-12 are pending and under examination.

Claims 1-12 are being acted upon as they recite a method comprising steps (a)-(h) of Claim 8.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record as set forth in Paper No. 7, mailed 7/15/02 and maintained in Paper No. 10, mailed 12/30/02.

Applicant's arguments, filed 6/02/03, have been fully considered but they are not persuasive. Applicant argues that the rejection must only apply to Claims 7 and 8.

Applicant is advised that the elected invention consists of a method comprising steps (a)-(h) of Claim 8. Accordingly the rejection is applied to all pending claims. See the Restriction, mailed 3/18/02 and Applicant's Election, filed 4/29/02.

Applicant argues, "the rejection appears to be based on the term being too broad."

Applicant is advised that the rejection is based on the term being undefined. See the Office action mailed 7/15/02. It remains the Examiner's position that "dendritic cell culture medium" comprises an undefined term, the metes and bounds of which cannot be determined in the instant context. For example, it is unclear whether the method would encompass a method in

which the cells were cultured in a medium such as RPMI 1640 supplemented with GM-CSF and TNF α .

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-12 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record as set forth in Paper No. 7, mailed 7/15/02 and maintained in Paper No. 10, mailed 12/30/02.

Applicant's arguments, filed 6/02/03, have been fully considered but they are not persuasive. Applicant argues that "Applicants maintain that it is an error to ignore the disclosure in the specification, in an enablement analysis. Applicants respectfully direct the Examiner's attention to MPEP §2164.08 which states that for an enablement analysis one "does not look to the claims but to the specification to find out how to practice the claimed invention."

It remains the Examiner's position that while the claims are read in light of the specification, it is the claims that define the invention. By Applicant's logic the claims need recite no limitations at all; in the instant case, "A method for reproducibly generating dendritic cells" would be sufficient. The MPEP makes clear that this sort of claim is not acceptable, "The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent." Additionally, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors [Wands], the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation." MPEP 216401(a).

Regarding said scope, the invention, as defined by the claims, is not enabled for its full scope. While Applicant argues that the specification discloses adequate guidance such as

"exemplary periods of incubation", the single disclosed example cannot support claims reciting such broad limitations as "incubating for a predetermined time period." And it is particularly noted that Applicant has chosen not to respond to the specific teachings set forth in the '756 patent regarding the criticality of the length of incubation. Instead, Applicant argues that the length of incubation cannot be considered critical because the specification does not disclose it as such. Applicant is advised that the specification is not read in a vacuum but in light of that which is known in the art. Again, by Applicant's logic, claims drawn to biomedical science's equivalent of the perpetual motion machine i.e., the "magic bullet", would be allowable as long as the specification did not raise any doubts as to enablement. Clearly, an invention cannot be considered enabled simply because of a lack of disclosure.

Thus, in regards to the failing of the claims to indicate which group of cells is saved and which group is discarded, the lack of the recitation of any time periods or ranges, the lack of the recitation of any specific reagents in the culture medium, and the failing to recite any ratio, or range of ratios, of microcarrier beads to culture volume, the rejection has been maintained.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
July 30, 2003